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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,266	04/05/2001	James G. Skakoon	723.041US1	4355

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EXAMINER

LAURITZEN, AMANDA L

ART UNIT	PAPER NUMBER
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3737

MAIL DATE	DELIVERY MODE
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07/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/827,266

Applicant(s)

SKAKOON ET AL.

Examiner

Amanda L. Lauritzen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-24,26-30 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-24,26-30 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

Response to Arguments

Applicant's arguments filed 20 February 2007 have been fully considered but they are not persuasive.

Regarding Applicant's statement that Rapoport does not teach MR compatibility, Examiner disagrees. Applicant states that the procedure is performed after an MR preoperative scan, and while this is true, Rapoport additionally teaches use of electromagnetic transmitters as a way of marking the target area during the procedure, and this suggests that the components of the apparatus must be compatible so as to not interfere in use (col. 9, lines 1-12). Furthermore, Taylor discloses image-directed (and therefore compatible) robotic systems as conventional in the art (col. 2, lines 21-26) and the system of Taylor is compatible itself in that it allows for image tracking of a surgical instrument (col. 4, line 62 – col. 5, line 6; also col. 6, lines 21-55). Additionally, in the Office action dated 27 February 2006, a provisional double patenting rejection was presented that cited a difference "in only the obvious variation of introducing an MR compatible cable...". This statement was not refuted by Applicant and, in fact, the pertinent claims of the instant application were amended to overcome this rejection, so it is also clear on the record that a difference of providing MR compatibility is obvious.

Regarding motivation to use a cable or shaft, such a design requires less physical space than functional equivalents used to couple the holder assembly to the advancer taught in Taylor and therefore it in fact does enhance accessibility to the surgical site. This motivation supports combination of the teachings of Taylor with those of Rapoport.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 2, 4-14, 16-18, 20-27, 29-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (U.S. 5,950,629) in view of Rapoport (U.S. 5,957,934).

Taylor et al. disclose all the features of the invention as substantially claimed including an MR-compatible, calibrated introducer device and associated method, the device comprising a guide unit having a linear range of motion (see fine motion manipulator 14 of Fig. 1A with linear motion section 68; also col. 8, lines 35-36); a holder assembly traveling along the range of motion of the guide unit capable of receiving attachment of a primary medical device (member 115 acts to hold surgical instrument through clamp 117 having an implied hole or opening; also col. 11, lines 34-36); a thumb wheel and/or rotating wheel advancer that translates rotation of the thumb wheel about a thumb wheel axis into motion of the holder assembly (fine motion manipulator 14 is interpreted as the thumb wheel advancer when operated manually, as in col. 7, lines 3-5). The apparatus of Taylor '629 further includes an indicator scale coupled to the thumb wheel that indicates the position of the holder assembly with a frameless locating attachment that includes a plurality of IR reflective spheres and or IR generating LED devices and IR sensitive camera (beacons 112 enable position determination as in col. 11, line 66 – col. 12, line 6; beacons contain LED devices or reflectors as in col. 11, lines 43-47). Taylor '629 further

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discloses a centering plate comprising at least two walls partially defining an opening in the plate wherein the centering plate can be adjusted to center the primary medical device (col. 10, lines 3-45 in which roll, pitch and yaw sections comprise plates 96 and 98 to provide orthogonally decoupled motions about the center point to position the medical instrument). Taylor also discloses a means for selectively locking and unlocking movement in col. 3, lines 48-49, which implies the locking device must be actuated before motion of holder assembly is permitted. The locking device of Taylor '629 is further capable of being selectively actuated in either a freewheeling mode or a discrete step mode (i.e., the locking device is freewheeling when motion is enabled in all degrees of freedom and discrete when locks are actuated for aligning select degrees of freedom as in col. 14, lines 9-28; refer also to col. 3, lines 63-67 for discrete locking in either locked or unlocked fashion).

Taylor et al. '629 further discloses a local position sensor that includes an encoder that is mounted to the guide unit that includes a remote user interface for display to the surgeon (col. 15, lines 22-26; col. 11, lines 62-66).

Taylor et al. cite trajectory guide systems such as that of patent '629 being capable of moving a surgical instrument through an exactly defined trajectory (co. 1, lines 35-37).

The disclosure of Taylor '629 does not include a cable mechanism to operatively couple the advancer to the holder assembly, but in the same field of endeavor, Rapoport '934 teaches coupling a motor 31 (i.e. advancer) to a guide tube 28 (i.e. holder assembly) via shaft 30 (i.e. cable as shown in Fig. 5; see also col. 7, lines 20-53). Therefore, it would have been obvious to one of ordinary skill in the art, at the time of invention to incorporate use of a cable to couple the advancer with the holder assembly as taught by Rapoport with the apparatus of Taylor '629 in

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lieu of a rigid fixture to enhance accessibility to the surgical site as taught by Rapoport at col. 7, line 53.

Regarding claim 9, though Taylor '629 does not particularly disclose discrete increments of the holder assembly of one-half millimeter, angular rotation of this device provides movement measured in degrees which corresponds to a linear displacement, and an example is offered in which the device is displaced in an increment of less than 0.5 mm, and therefore increments of any larger step could be accomplished with appropriate angular rotation by both the fine and coarse adjustments (for example, see col. 11, lines 14-19).

2. Claims 15, 19 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor '629 in view of Rapoport '934 and Stark et al. (U.S. 5,823,975).

The invention of Taylor as modified by the teachings of Rapoport includes all features of the instant invention as substantially claimed, but is not specific to use of a potentiometer to sense position with a device mounted coil; however, Stark et al. teach using a potentiometer with a device mounted coil to solve the same problem of position determination (col. 6, line 67 and col. 7, line 1). It would have been obvious to use a potentiometer and a spring for the purpose of position sensing as taught by Stark in order to monitor component displacement as a function of a change in output resistance (at Stark col. 7, lines 62-66).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


ALL
6/27/2007


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